

REMARKS

Claims 1, 4 to 16 and 21 are pending in the subject application. Applicants have hereinabove amended claim 6 and cancelled claim 4 without prejudice to their right to pursue the cancelled subject matter in a later filed divisional or continuation application. Entry of this Amendment and reconsideration of the application as amended are respectfully requested. Upon entry of this Amendment claims 1, 5 to 16 and 21 are pending.

Applicants respectfully submit that the amendment of the claims of the subject matter does not include new matter and request that the amendments be entered. Applicants will be discussing the amendments to the claims in their remarks below.

I. RESPONSE TO REJECTION UNDER 35 U.S.C. U.S.C. §103(A)

The Examiner on page 2 of the June 12, 2003 Office Action maintained his rejection of the claims under 35 U.S.C. §103(a) as allegedly being unpatentable over Kath et al. (U.S. Pat. No. 6,284,764 B1)(hereinafter "the '764 patent"). Applicants respectfully traverse the Examiner's rejection of the claims of the instant application under 35 U.S.C. §103(a), in view of the '764 patent for the following reasons.

Applicants respectfully submit that the Examiner is improperly applying the '764 patent against the instant invention in contravention of 35 U.S.C. §103. Applicants direct the Examiner's attention to MPEP §706.02(k) excerpted below for the Examiner's convenience.

Effective November 29, 1999, subject matter which was prior art under former 35 U.S.C. 103 via 35 U.S.C. 102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." (Emphasis added). This change to 35 U.S.C. 103(c) applies to all utility, design and plant patent applications filed on or after November 29, 1999, including continuing applications filed under 37 CFR 1.53 (b), continued prosecution applications filed under 37 CFR 1.53 (d), and reissues. The amendment to 35 U.S.C. 103(c) does not affect any application filed before November 29, 1999, a request for examination under 37 CFR 1.129 of such an

application, nor a request for continued examination under 37 CFR 1.114 of such an application. The changes to 35 U.S.C. 102(e) in the Intellectual Property and High Technology Technical Amendments Act of 2002 (Pub. L. 107-273, 116 Stat. 1758 (2002)) did not affect the exclusion under 35 U.S.C. 103(c) as amended on November 29, 1999. See MPEP §706.02(l)(1) for additional information regarding disqualified prior art under 35 U.S.C. 102 (e)/103.

Applicants respectfully submit that the '764 patent qualifies as prior art to the instant application under 35 U.S.C. §102(e). Applicants note that the 35 U.S.C. §102(a) and 35 U.S.C. §102(b) dates for the '764 patent is its publication date as a patent on September 4, 2001. The instant application predates the '764 patent the 35 U.S.C. §102(a) and 35 U.S.C. §102(b) date by over 14 months, i.e., earliest effective filing date of the instant application is June 20, 2000. Therefore, the '764 patent does not qualify as prior art to the instant application under 35 U.S.C. §102(a) and 35 U.S.C. §102(b).

With respect to 35 U.S.C. §102(e), as recited in MPEP §706.02(k), section 102(e) has been added to the common ownership prior art disqualifier in 35 U.S.C. §103(c). Applicants respectfully submit that the instant application and the '764 patent are subject to an obligation of assignment to the same person, i.e., Pfizer Inc. Accordingly, the '764 patent does not qualify to be applied against the instant application in a 35 U.S.C. §103(a) rejection due to the exemption provided for commonly owned prior art under 35 U.S.C. §102(e) in 35 U.S.C. §103(c). Accordingly, applicants' respectfully request the Examiner to reconsider and withdraw the application of the 35 U.S.C. §103(a) rejection based upon the '764 patent in view of the preceding remarks.

II. REJECTION UNDER THE JUDICIALLY CREATED DOCTRINE OF OBVIOUS-TYPE DOUBLE PATENTING

On page 6 of the Office Action the Examiner maintained his rejection of claims 1, 4, 5, 7-11 and 21 of the subject application under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-20 of the '764 patent. The Examiner further states that the alleged conflicting claims are not identical, they are not patentably distinct from each other for the reasons provided in the section 103(a) rejection of

the June 12, 2003 Office Action. Applicants respectfully traverse the Examiner's rejection of the claims of the instant application over the '764 patent for the following reasons.

Applicants respectfully submit that the Examiner has not yet provided applicants with an obviousness-type double patenting rejection analysis of the claims of the subject matter that provides the facts based upon the claims of the '764 patent which support such a rejection. As noted in MPEP Section 804: "[b]ecause there are significant differences between a rejection based on double patenting and one based on prior art under 35 U.S.C. 102(e)/103 over the same issued patent, it is both appropriate and necessary that an examiner make both rejections when the facts support both rejections." The Examiner has merely referred applicants to his rejection based upon the 103(a) rejection, which as noted above is not applicable to the instant application.

The test for double patenting of the obviousness type is whether the **later claim** defines an obvious variation of the earlier claim. *In re Emert*, 44 USPQ 1149, 1152 (Fed. Cir. 1997). In such an analysis the specification underlying the earlier claim made the basis of the rejection is not considered to be prior art; only the subject matter of the earlier claim is considered to be the basic prior art reference. *Quad Env'tl. Tech. Corp. v. Union Sanitary Dist.*, 20 USPQ2d 1392, 1394 (Fed. Cir. 1991). Accordingly, in a double-patenting rejection the principal reference is limited to the subject matter of the earlier claim.

Applicants respectfully submit that the claims of the instant application are not an obvious variation of the issued claims of the '764 patent. The claims of the '764 patent are directed to quinazoline derivatives whereas the claims of the instant application are directed to a particular set of quinazoline derivatives. More particularly, the claims of the instant application are directed to particular quinazoline derivatives having a particular set of R³ substituents directly attached to a phenyl substituent of the quinazoline. Applicants respectfully submit that the Examiner has not provide any underlying facts or rationale based upon the claims of the '764 patent whey the claims of the instant application are obvious variations thereof. Although, the Examiner did provide remarks concerning the 102(e)/103 rejection those remarks are premised upon identification of subject matter from the specification not the claims.

The Examiner is required to provide the necessary motivation based upon the claims of the '764 patent. The Examiner is using an obvious to try standard by asserting that the claims in the '764 patent makes it obvious to make the claimed invention. More is required. The Examiner needs to point to a motivation or suggestion in the claims of the '764 patent that suggests the compounds of the claimed invention. The Examiner has not done so. The

Examiner has failed to provide reasons why one of ordinary skill in the art would conclude that the invention in the instant application is an obvious variation of the invention defined in the claims of the '764 patent. Why would one of ordinary skill in the art select the particular elements claimed in the instant application based upon the claims of the '764 patent? Applicants respectfully submit that those of ordinary skill in the art have a multitude of choices based upon the claims of the '764 patent.

The doctrine of double patenting is intended to prevent a patentee from obtaining a time-wise extension of patent for the same invention or an obvious modification thereof. e.g., *In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985). Applicants respectfully submit that issuance of the claims of the instant application will not result in a time-wise extension of a patent for the same invention. The claims of the instant application are patentable distinct from those of the '764 patent. The compounds claimed in the instant application are distinct from those claimed in the '764 patent claims. Accordingly, applicants are not receiving an extension of the claimed subject matter in the '764 patent by issuance of the claims of the instant application.

Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under obviousness-type-double patenting in view of the claims of the '764 patent. If the Examiner maintains his double patenting rejection of the claims of the subject application, applicants respectfully request that the Examiner inform applicants with the underlying facts and reasoning supporting his double-patenting rejection of the obviousness type.

III. RESPONSE TO REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

On page 7 of the Action the Examiner maintained his rejection of claims 1, 4-16 and 21 under 35 U.S.C. §112, first paragraph as allegedly not providing enablement for solvates. The Examiner asserts that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with the claims.

The Examiner states "that the claims are drawn to solvates and that hundreds of examples are presented all failed to produce solvates. These cannot be willed into existence." The Examiner cited in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 for the proposition "[t]he specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is

no evidence that such compounds exist ... the examples of the ‘881 patent do not product the postulated compounds ... there is ... no evidence that such compounds exist.”. The Examiner then asserts that “the same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have been formed. Hence, applicants must show that solvates can be made, or limit their claims accordingly.” (Emphasis added).

The Examiner further states on page 7 of the June 12, 2003 Office Action that “all attempts to prepare solvates failed.” The Examiner concedes on page 7 of the Action that applicants’ statement that the preparation of solvates is well known is correct (“it is not uncommon to have solvents such as methylene chloride ... forming solvents with organic compounds prepared in these solvents.”). However, the Examiner asserts that the evidence of the record demonstrates that the particular compounds do not form solvates.

Applicants respectfully disagree with the Examiner’s position, characterization of the teachings of the subject application and the application of Morton to the instant application.

With respect to the Examiner’s position that the compounds of the claimed invention do not form solvates the only proffered evidence is the lack of a particular solvate example in the specification of the subject application and the Examiner’s statement that “all attempts to prepare solvates failed”. Applicants are at a loss for the basis of this statement by the Examiner. On what basis is the Examiner concluding that “all attempts to prepare solvates failed”. The Examiner is making a finding without any underlying support for such a position. Applicants have not stated that attempts to prepare solvates failed. This is the Examiner’s own personal statement not based on intimate knowledge of the discovery and preparation of the claimed compounds. Applicants respectfully submit that this statement by the Examiner has no basis in fact.

In order to satisfy 35 U.S.C. 112 requires that an invention be described in such full, clear, concise, and exact terms as to enable any person skilled in the art to make and use the claimed invention. Applicants have complied with section 112 and as acknowledged by the Examiner the preparation of solvates is well known (See, page 7 of the Action “[a]pplicants state correctly that the preparation of solvates is well known, and that it “is not uncommon to have solvents such as methylene chloride ... forming solvates with organic compounds prepared in these solvents.”). In essence the Examiner is acknowledging that the knowledge to make solvates is well known to those of ordinary skill in the art. The Examiner seems to be maintaining his 112 rejection based on his own belief that it is not possible to make

solvates of the claimed compounds since none are expressly exemplified by applicants in the instant application. The Examiner then places the burden on applicants to prove their existence. This is not required under the law nor has the Examiner cited any case law or rule permitting him to require applicants set forth such evidence.

Applicants again reiterate solvates are well known to those of ordinary skill in the art. It is well known to those of ordinary skill in the art that isolation of compounds in the solid state may result in solvent bound in the solid state (either in crystalline or amorphous forms). It is not uncommon to have solvents such as methylene chloride, ethyl acetate, acetonitrile or methanol forming solvates with organic compounds prepared in these solvents. Preparation of solvates of compounds is well known and understood by those of ordinary skill in the art. Nothing further is required.

Applicants respectfully request the Examiner identify what rule, case law or precedent he is relying on to support his statement on page 7 of the Office Action: “[h]ence, applicants must show that solvates can be made.” Applicants recognize that the Examiner is attempting to use Morton to support his position. However, the case is not applicable and deals with a completely different factual situation than the present case.

In Morton the claims related to particular heat stabilizers in two patents which were allegedly organotin compounds, more particularly organotin mercaptoalkyl carboxylic acid ester sulfides. For the purpose of this response applicants have excerpted claim 1 (only claim at issue in both patents) which was presented by the Court as representative for its purposes.

1. A monoorganotin or diorganotin mercaptoalkyl ester of a carboxylic acid or mercapto hydroxyalkyl ester of a carboxylic acid mono or polysulfide useful as a stabilizer for improving the resistance to deterioration of vinyl chloride polymers when heated at 350°F, containing at least one tin atom [sic, atom] having one to two hydrocarbyl groups having from 1 to 20 carbon atoms and selected from the group consisting of alkyl, aryl, cycloalkyl, aralkyl and alkenyl and linked to the tin through carbon, at least one mercaptoalkyl ester of a carboxylic acid group linked to tin through the sulfur of the mercaptoalkyl group and at least one mono or polysulfide sulfur group bonded exclusively to tin, the organotin compound having an amount of tin within the range from 10 to 42% by weight and an

amount of sulfur within the range from 8 to 42% by weight.

The claim in the '881 patent as shown above provides for functional claim language and percentage by weight limitations for tin and sulphur for the claimed compounds. The Court notes that the specification of the '881 patent "purports to teach, with over fifty examples, the preparation of the claimed compounds, with the required connectivity". The Court continues by stating that the district court found that

[e]ven with the aid of sophisticated analytical instrumentation and the use of model systems which attempt to provide the compounds prepared in the '881 patent, however, there is no evidence that such compounds exist. The clear and convincing evidence has shown that the Examples of the '881 patent do not produce the postulated compounds. Rather, the examples and procedures produce a complex mixture of alkyltin mercaptides and alkyltin sulfides. The evidence established that a number of these are prior art compounds known to be useful as heat stabilizers.

The Court concludes that "there is considerable evidence shown that those skilled in the art could not make the claimed compounds using the procedures of the specification, and no evidence that such compounds even exist. The fifty-odd examples in the patent obviously teach something, but the evidence shows that they do not teach what was allegedly defined in the claims." Applicants respectfully submit that that Examiner's reliance upon Morton is misplaced and not applicable to the claims of the instant application.

Morton's starting principal is that even with the aid of sophisticated and use of modeling equipment the existence of the claimed compounds could not be established. Morton attempted to claim discrete and well-defined organotin compounds but his examples and procedures resulted in the formation of organotin complexes. This is not the case here. Applicants have provided a large number of representative examples including their experimental preparation details and supporting analytical data to verify their existence. In contrast Morton's procedures from the specification resulted in the formation of complexes not the claimed compounds. The preparation of solvates in the instant application is merely the preparation of additional compounds well within the scope and skill of those of ordinary skill in the art.

The compounds claimed in Morton were not well characterized and do not defined

well-characterized organic molecules as found in the present application. The instant application provided experimental methods, procedures and analytical data for the compounds of formula 1. There is no doubt that applicants' claimed compounds exist, whereas Morton's compounds *ab initio do not exist*. While applicants have not provided a representative example of a solvate of formula 1 that in of itself does not establish the negative, i.e., that they cannot be made. The Examiner provided no underlying scientific logic, rationale or evidence to support his position that solvates of the compounds of formula 1 cannot be made except for the absence of a representative example. On what scientific basis, principal, or fact is the Examiner so convinced that solvates of the compounds of the claimed invention cannot be made?

Applicants are at a loss for the basis of the Examiner's statement that "applicants must show that solvates can be made". Where in the patent laws does it state that an applicant is required to provide the existence of this compound or any other compound that are readily prepared by those of ordinary skilled in the art? For that matter a patent application directed to organic compounds could be comprised of only prophetic examples. Applicants are not required to provide examples that have been reduced to practice in the laboratory when those of ordinary skill in the art could practice the invention without undue experimentation. The Examiner acknowledges that preparation of solvates is well known by those of ordinary skilled in the art. If the Examiner requires applicants "must" show that solvates exist then applicants would appreciate knowing where the Examiner is finding support for such a requirement.

Additionally, the Examiner of the instant application has issued patents in the past including claims directed to compounds and solvates which are identically situated as the present application, i.e., no representative solvate example was provided in the specification. For example, U.S. Patent No. 6,316,444, issued on November 13, 2001, with claims directed to pyrimidine compounds of a formula I, pharmaceutically acceptable salts, hydrates, solvates, crystal forms and individual diastereomers thereof. The examples provided in the '444 patent do not include examples of solvates of the compounds of formula I. Does that necessarily mean that the absence of an example of a solvate means that there is no evidence of the existence of solvates? The Examiner appears to have found in the '444 patent that solvates exist since claims were allowed and issued with such claim language. Applicants respectfully submit that the '444 patent and the instant application are similarly situated in that neither has a particular example of a solvate, however, that fact in of itself does not mean

that those of ordinary skilled in the art could not prepare such compounds. Accordingly, applicants respectfully request that the Examiner reconsider the applicability of the 35 U.S.C. §112 rejection of the claims of the subject invention in view of the preceding remarks.

IV. RESPONSE TO CLAIM OBJECTIONS

On page 8 of the Action the Examiner objected to claims 4 and 6 under 37 C.F.R. §1.75(c) as being improper dependent form for failing to further limit the subject matter of the previous claim. The Examiner states that claim 4 is now identical to amended claim 1 and thus fails to further limit. Applicants thank the Examiner for pointing out applicants' inadvertent oversight when they amended claim 1 in the previous response by incorporating the limitations of dependent claim 4. Applicants have now hereinabove canceled claim 4, thus rendering this claim objection moot. The Examiner stated that claim species of claim 6 at page 79, lines 10-28 are now provided for in claim 1 as pyrazines are not in the amended R³ choices for claim 1. Applicants have hereinabove as suggested by the Examiner amended claim 6 to exclude pyrazines, thus rendering this objection moot. Applicants respectfully request the Examiner reconsider and withdraw his objections of claims 4 and 6 in view of the preceding remarks.

CONCLUSION

For the reasons set forth hereinabove, applicant respectfully requests that the Examiner reconsider and withdraw rejections and objection setforth in the June 12, 2003 Office Action and earnestly solicit allowance of the claims pending in the subject application.

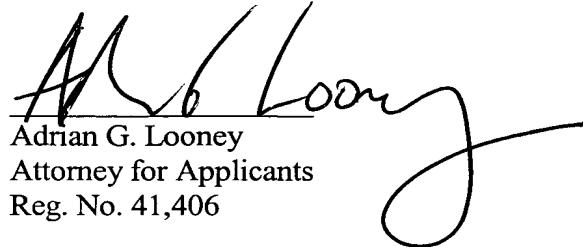
Applicants do not believe any fee(s) other than those listed on the fee transmittal sheet are due in connection with this Amendment to the June 12, 2003 Action, however, if any additional fee(s) is due applicants' attorney authorizes payment from deposit account number 16-1445 or credit any overpayment to the aforementioned deposit account.

**Patent Application
Attorney Docket No. PC10760A
U.S. Serial No. 09/883,752**

If the Examiner wishes to comment or discuss any aspect of this application or response, applicants' undersigned attorney invites the Examiner to call him at the telephone number provided below.

Respectfully submitted,

Date: December 11, 2003


Adrian G. Looney
Attorney for Applicants
Reg. No. 41,406

Pfizer Inc.
Patent Department, 5th Floor
150 East 42nd Street
New York, NY 10017-5755
(212) 733-1038